ReliOn®
Live Your Best For Less.

ULTIMA
Blood Glucose Monitoring System

User's Manual
For *in vitro* diagnostic use

Table of Contents

Intended Use

The ReliOn Ultima Blood Glucose Monitoring System is intended for *in vitro* diagnostic use in the quantitative measurement of glucose in fresh whole blood for self-testing by lay users (e.g., from the finger, forearm, upper arm or base of thumb), or by health care professionals. It is not intended to be used for testing neonatal blood samples. The ReliOn Ultima system is indicated for home (lay user) or professional use in the management of patients with diabetes.

The system is not for use in diagnosis or screening of diabetes mellitus, but is to be used as an aid in monitoring the effectiveness of diabetes control programs.

> **IMPORTANT:** Use only **ReliOn Ultima** blood glucose test strips. Other test strips may produce inaccurate results.

IMPORTANT: See test strip instructions for use for more information about sample types.

Potential infection risk: Healthcare professionals performing blood tests with this system on multiple patients must always wear gloves and should follow the infection control policies and procedures approved by their facility.

Read the instructions in this user's manual. Failure to follow instructions may cause incorrect results. Practice the testing procedures before using the meter. Follow your healthcare professional's advice when testing blood glucose levels.

Warning: Test on your fingers if you are testing for hypoglycemia (low blood glucose) or if you suffer from hypoglycemia unawareness.

Observe caution when using around children. Small parts may constitute a choking hazard.

How Your ReliOn Ultima Blood Glucose Monitoring System Works

When you insert a test strip into your meter, the Apply Sample message shows on your meter's display window. When a blood sample or control solution sample is applied to the test strip, the glucose reacts with the chemicals on the test strip. This reaction produces a small electrical current that is measured. The result shows on your meter's display window.

IMPORTANT: Avoid getting dust, dirt, blood, control solution, water or any other substance in the meter's test strip port.

Important Health-Related Information

Low or high blood glucose results can indicate a potentially serious medical condition. If your blood glucose result is unusually low or high, or if you do not feel the way your result indicates, repeat the test with a new test strip. If your result is not consistent with your symptoms or if your blood glucose result is less than 50 mg/dL or higher than 300 mg/dL you should contact your healthcare professional and follow his or her treatment advice.

The expected glucose range for a non-diabetic, non-pregnant fasting adult is under 100 mg/dL.[1] Two hours after meals, levels should be less than 140 mg/dL.[1] Consult your healthcare professional to determine the range that is appropriate for you.

Monitoring System Kit Contents

Monitoring System Kit contains:

- Meter
- User's Manual
- Lancets
- Logbook
- Warranty Card
- Carrying Case
- Lancing Device

Items not included:

- Blood Glucose Test Strips
- Control Solutions
- Data Management System

Setting Up the Meter

Enter Setup Mode

	Start with the meter off (no test strip inserted).	**Commands** • Press ① to move between setup displays • Press ▶ to move forward • Press ◀ to go back • Press ☀ to turn display light On and Off
√ ♫	Press and hold ① until √ and ♫ appear. This indicates the beeper is turned on.	
✗ ♫	✗ and ♫ indicate the beeper is turned off.	

Beeper

Press ◀ or ▶ to change the beeper setting.
Press ① to save the beeper setting and move
to set time.

The beeper sounds when:
• The test countdown starts
• The test countdown ends

Time

12:00 AM

The hour flashes. Press ◀ or ▶ until the correct hour appears. Press ① to save the hour and to move to set minutes.

The minutes flash. Press ◀ or ▶ until the correct minutes appear. Press ① to save the minutes and to move to set date.

Date

20 10
Year

10- 1
Month – Day

The year flashes. Press ◀ or ▶ until the correct year appears. Press ① to save the year and to move to set month.

The month flashes. Press ◀ or ▶ until the correct month appears. Press ① to save the month and to move to set day.

The day flashes. Press ◀ or ▶ until the correct day appears. Press ① to save the day and to move to set time format.

Time Format

22:00
24 Hour Format

Note: *If using the 12-hour time format, AM and PM appear.*

The time format flashes. Press ◀ or ▶ to change the time format. Press ① to save the time format and to move to set date format.

Date Format

10-15 Month – Day **15.10** Day.Month	The date format flashes. Press ◀ or ▶ to change the date format. Press ① to save the date format and to move to the measurement units.

> **IMPORTANT:** Please check that the correct time and date is set before you use the meter for the first time. This will help you keep records of when you monitor and will help you and your healthcare professional make informed decisions about your care. **You must set the time and date to review averages**.

Measurement Units

mg/dL	The unit of measurement set by the factory appears. You cannot change this setting. Contact Customer Service for more information. Press ① to return to set beeper, or press and hold ① to turn off the meter.

Testing Your Blood Glucose

Important Testing Notes
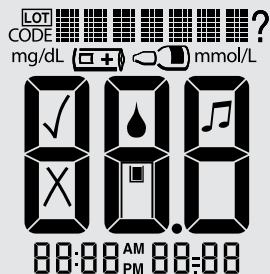
This display always appears when the meter is turned on. You should check that your meter matches the example you see here exactly every time your meter turns on.

Do not use the meter if the display check screen does not exactly match the example.

If the screen does not match, the meter may show an incorrect result. Please contact Customer Service.

E.g. Expiration date: March 31, 2012

- Use the meter within the test strip operating range
- Use the test strip immediately after removing it from its foil packet
- Use each test strip only once

LOT 13758
EXP 2012/03

E.g. Expiration
date: March 31,
2012

Do not use expired test strips; they may produce inaccurate results.
The expiration date is the last day of the month if only the month and
year are shown.
Do not use a wet, bent, scratched or damaged test strip.
Do not use the test strip if its foil packet has a puncture or tear in it.

Note: See test strip instructions for use for operating range and more information on limitations of use.

Test Site

Fingertips

IMPORTANT: Wash your hands and the test site with warm soapy water to ensure accurate results. Thoroughly dry your hands and the test site. To warm alternate sites, apply a warm dry pad or rub vigorously for a few seconds.

Note: When obtaining blood samples from alternate sites, avoid areas near bones, areas with lots of hair, and squeezing the puncture site. Bruising may occur at alternate sites, but will disappear quickly. If bruising occurs, consider selecting another site.

Finger tip testing is different from alternate site testing. (Adjust the lancing device accordingly for testing site. See lancing device instructions for use for more information.)

Alternate Sites

Base of thumb
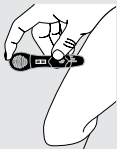
Upper arm

Forearm

You may obtain a blood sample from alternate sites – forearm, upper arm, and base of the thumb. Results from alternate sites are subject to limitation. Contact your healthcare professional before beginning alternate site testing.

- Alternate site results may differ from fingertip results when blood glucose levels change rapidly (e.g. after eating a meal or taking insulin, or during or after exercise)
- Use alternate sites before, or more than two hours after, you eat a meal, take insulin, or exercise

> **Do not** use blood samples from alternate sites when:
> - You think your blood glucose is low or changing rapidly
> - You have been diagnosed with hypoglycemia unawareness
> - Alternate site results do not match the way you feel
> - You are within two hours of eating a meal, taking insulin, or exercising

Performing a Blood Glucose Test
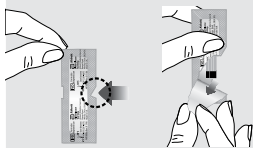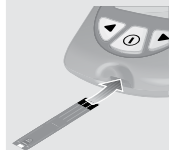
	Open the foil test strip packet at the notch and tear down to remove the test strip.
	Insert the Test Strip With the contact bars (3 black lines) facing up, insert the test strip into the meter until it stops. This turns on the meter. *Note: The meter turns off after 3 minutes of inactivity. Remove and reinsert the unused test strip to restart the meter.*
	This display always appears when the meter is turned on. **Do not use the meter if the display check screen does not exactly match the example. Contact Customer Service.** See "Testing Your Blood Glucose" section for more information.
10:30ᴬᴹ 12-5	Time and date (if set) appear next.

LOT 00000 and the Apply Sample symbols 🌢 and ⊔ appear next, indicating the meter is ready for you to apply a sample to the test strip.

Obtain a Blood Sample
Select a test site. Use the lancing device to obtain a blood sample. (See lancing device instructions for use for more information.)

Apply Blood to the Test Strip
Bring the blood drop to the white area at the end of the test strip. The blood is drawn into the test strip.

> **IMPORTANT:** If the count down does not start, you may not have applied enough blood to the test strip. See test strip instructions for use for re-application instructions. If the countdown still does not start, remove the used strip and discard it properly. Start a new test with a new test strip.

Hold the blood drop to the white area until the meter beeps (if sound is on) and the status bar appears on the display. This indicates the test strip has obtained enough blood.

The countdown appears on the display as the meter checks your glucose level.

Note: Do not remove the test strip from the meter or disturb the test strip during the countdown.

View the Result

The meter beeps (if sound is on) when the result appears on the display. The test is complete (example shown). The result is stored in memory or you can write it in a logbook.

Turn Off the Meter

Use the opened foil packet to remove the used test strip. This turns off the meter. Discard the used test strip properly.

Note: You can also press and hold ① for at least 2 seconds to turn off the meter. The meter also turns off after 60 seconds of inactivity.

Understanding Blood Glucose Test Results

Low and High Blood Glucose Results

The meter displays results in mg/dL. The unit of measurement is preset. You cannot change this setting.

> **IMPORTANT:** The meter displays results from 20–500 mg/dL. Low or high blood glucose results can indicate a potentially serious medical condition.

General:

Result	What It Means	What To Do
Lower than 50 mg/dL	Low (hypoglycemic)	If you have symptoms such as weakness, sweating, nervousness, headache or confusion, then follow your healthcare professional's recommendation to treat hypoglycemia. If you have no symptoms of low blood glucose, then repeat the test with a new test strip on your fingers. If the result is lower than 50 mg/dL, perform a control solution test to ensure your system is functioning properly. If the system is functioning properly follow your healthcare professional's recommendation to treat hypoglycemia.

Result	What It Means	What To Do
Higher than 300 mg/dL	High (hyperglycemic)	If you have symptoms such as fatigue, thirst, excess urination, or blurry vision, then follow your healthcare professional's recommendation to treat hyperglycemia. If you have no symptoms of high blood glucose, then repeat the test with a new test strip on your fingers. If the result is higher than 300 mg/dL, perform a control solution test to ensure your system is functioning properly. If the system is functioning properly follow your healthcare professional's recommendation to treat hyperglycemia.

Meter:

Display	What It Means	What To Do
LO Appears when result is: Lower than 20 mg/dL	Severe low blood glucose or There may be a problem with the test strip	Repeat the test with a new test strip. If the result is LO, contact your healthcare professional **immediately**.
KETONES? Appears with result which is: Higher than or equal to 300 mg/dL	Blood glucose level is high	Repeat the test with a new test strip. If the result appears again, follow your healthcare professional's instructions.

Display	What It Means	What To Do
HI Appears when result is: Higher than 500 mg/dL	Severe high blood glucose or There may be a problem with the test strip	Repeat the test with a new test strip. If the result is HI, contact your healthcare professional **immediately**.

Note: If you see the error messages E-3 or E-4, consult the Error Messages section in this user's manual.

IMPORTANT: Contact your healthcare professional if you have symptoms that **do not** match your test result, and you have followed the instructions in this user's manual.

MediSense Glucose Control Solutions

IMPORTANT: When you open a control solution bottle for the first time, count forward 90 days and write this date on the control solution bottle using a pen that won't smear or wipe off. Throw away any remaining solution after this date.

Control solutions may be used with glucose test strips.
Use control solution:

• When using the meter for the first time

• To practice testing without using your own blood

• To confirm that the meter and test strips work together properly

• When your test results do not agree with how you feel

• When opening a new box of test strips

• When you get a HI or LO result

There are three levels of control solution available (Low, Mid, High). Contact Customer Service for information on how to obtain control solutions.

Important Control Solution Testing Notes

- Use only MediSense control solutions with the meter
- Replace the cap securely on the bottle immediately after use

> **Do not** use control solution past the expiration date.
> **Do not** add water or other liquid to control solution.
> **Do not** swallow or inject the control solution.
> **Do not** use the control solution as eye drops.

> **IMPORTANT:** Control solution results should fall within the control solution range printed on the test strip instructions for use. Check that the lot number printed on the test strip packet and instructions for use match.
> The control solution range is a target range for control solution only. It is not a target range for your blood glucose level. Control solution tests are specified to be accurate only when used between 59° and 104°F (15° and 40°C).
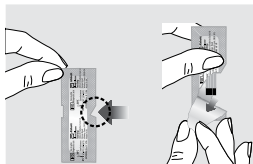
- Repeat the test if control solution results are outside this range
- Stop using the meter if control solution results are continually outside the range printed on the test strip instructions for use. Contact Customer Service

> **IMPORTANT:** Control solution results do not reflect your blood glucose level.
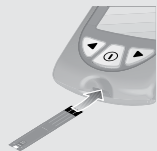
For Healthcare Professionals

- Use three levels of control solution to do control solution tests with each new box of test strips
- Ensure that quality control is performed in accordance with Federal, state and local guidelines

Performing a Control Solution Test

Open the foil test strip packet at the notch and tear down to remove the test strip.

Insert the Test Strip

With the contact bars (3 black lines) facing up, insert the test strip into the meter until it stops. This turns on the meter.

Note: The meter turns off after 3 minutes of inactivity. Remove and reinsert the unused test strip to restart the meter.

|	
	This display always appears when the meter is turned on. **Do not use the meter if the display check screen does not exactly match the example. Contact Customer Service.** See "Testing Your Blood Glucose" section for more information.
10:30ᴬᴹ 12-5	Time and date (if set) appear next.
ᴸᴼᵀ 00000 ● ⊓	LOT 00000 and the Apply Sample symbols ● and ⊓ also appear.
ᴸᴼᵀ 00000 ⊂▣ ● ⊓	Press ⓘ to mark the test as a control solution test. The ⊂▣ appears. The meter is now ready for you to apply control solution to the test strip. **IMPORTANT:** The test result will be saved to memory as a blood glucose result if not marked as a control solution test. This may affect your blood glucose averages.
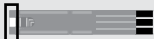
Apply Control Solution to the Test Strip

Shake the control solution bottle to mix the solution. Apply a drop of control solution to the white area at the end of the test strip in the area shown. The control solution is drawn into the test strip.

Hold the control solution drop to the white area until the meter beeps (if sound is on) and the status bar appears on the display. This indicates the test strip has obtained enough control solution.

The countdown appears on the display as the meter checks the glucose level.

*Note: **Do not** remove the test strip from the meter or disturb the test strip during the countdown.*

If the countdown does not start, remove and discard the used test strip, turn off the meter and try again with a new strip.

mg/dL

104

12:10 PM 10-20

View the Result

The meter beeps (if sound is on) when the result appears on the display. The test is complete (examples shown). The result is stored in memory as a control solution result or you can write it in a logbook as a control result.

Compare the control solution result to the range printed on the blood glucose test strip instructions for use. The result should fall within the range.

Causes of out-of-range results include:

• The meter and test strips may not be working properly

Repeat the test with a new test strip. Follow the testing instructions carefully. Contact Customer Service if the result is still outside the printed range.

Turn Off the Meter

Use the opened foil packet to remove the used test strip. This turns off the meter. Discard the used test strip properly.

Note: You can also press and hold ① for at least 2 seconds to turn off the meter. The meter also turns off after 60 seconds of inactivity.

Managing Your Results

Meter memory stores up to 450 events – control solution and blood glucose results, and other meter information. The most recent events appear first.

Viewing Test Results in Memory

Start with the meter off (no test strip inserted).

Press ① to turn the meter on.

This display always appears when the meter is turned on.

Do not use the meter if the display check screen does not exactly match the example. Contact Customer Service.

See "Testing Your Blood Glucose" section for more information.

MEM mg/dL **104** 9:49ᴬᴹ 10-26	Your most recent result, with time and date (if set) it was obtained, appears next. The following symbols indicate the type of result: MEM = Blood glucose result MEM = Glucose control solution result
	Press ◀ to review the previous result. Repeat this for each result you wish to review. **Note:** *To exit meter memory at any time, press and hold ①.*
MEM ━ ━ ━	Appears on the display when there are no previous results to view.
	Press ▶ to return to a previously reviewed result. Repeat this for each result you wish to review. **Note:** *To exit meter memory at any time, press and hold ①.*

Viewing Blood Glucose Averages

IMPORTANT:

- Set the date and time before testing to be able to review averages
- Averages do not include glucose control solution results and results that do not show time and date
- Control solution results not marked as control solution tests may cause averages to be inaccurate
- ▬ ▬ ▬ appears on the display when there are no current averages to view
- L0 blood glucose test results appear in averages as 20 mg/dL
- HI blood glucose test results appear in averages as 500 mg/dL

While in memory, press ①. Your 7-day average appears.

Note: *n = number of results included in your 7-, 14-, or 30-day average.*

Press ◀ to view the 14-day average.

Press ◀ to view the 30-day average.

Press ◀ to return to the 7-day average, or

Press ① to return to the memory screen.

Press and hold ① to turn off the meter. The meter turns off after 30 seconds of inactivity.

Transferring Results to a Computer

Transferring test results to a computer requires a compatible data management system. For more information, please go to our website or contact Customer Service.

Error Messages

Message	What It Means	What To Do
E- 1	The temperature is too hot or too cold for the meter to work properly	1. Move the meter and test strips to a location where the temperature is within the test strip operating range. (See test strip instructions for use for the appropriate range.) 2. Wait for the meter and test strips to adjust to the new temperature. 3. Repeat the test using a new test strip. 4. If the error reappears, contact Customer Service.
E-2	Meter error	1. Turn off the meter. 2. Repeat the previous testing steps. 3. If the error reappears, contact Customer Service.

Message	What It Means	What To Do
E-3	The blood glucose level may be too low to be read by the system or There may be a problem with the test strip	1. Review the testing instructions. 2. Repeat the test using a new test strip. 3. If the error reappears, contact your healthcare professional **immediately**.
E-4	The blood glucose level may be too high to be read by the system or There may be a problem with the test strip	1. Repeat the test using a new test strip. 2. If the error reappears, contact your healthcare professional **immediately**.
E-5	Blood was applied to the test strip too soon	1. Review the testing instructions. 2. Repeat the test using a new test strip. 3. If the error reappears, contact Customer Service.

Message	What It Means	What To Do
E-6	Meter error	1. Check that you are using the correct strip for this meter. (See test strip instructions for use to verify your strip is compatible with this meter.) 2. Repeat the test using a test strip for use with your meter. 3. If the error reappears, contact Customer Service.
E-7	No coding required or Test strip may be damaged, used, or the meter does not recognize it	1. Check that you are using the correct test strip for this meter. (See test strip instructions for use to verify your strip is compatible with this meter.) 2. Repeat the test using a test strip for use with your meter. 3. If the error reappears, contact Customer Service.
E-8 or E-9	Meter error	1. Turn off the meter. 2. Repeat the previous testing steps. 3. If the error reappears, contact Customer Service.

Troubleshooting

	What It Means	What To Do
The meter does not enter test mode after inserting a test strip.	Test strip is not inserted correctly or fully into the meter	1. With the contact bars (3 black lines) facing up, insert the test strip into the meter until it stops. This turns on the meter. 2. If the meter still does not enter test mode, contact Customer Service.
	No battery is installed Battery is installed incorrectly	1. Install battery with (+) facing up.
	Dead battery	1. Replace battery. Reset date and time, if necessary.

	What It Means	**What To Do**
The test does not start after applying the blood sample.	Blood sample is too small	1. See test strip instructions for use for re-application instructions. 2. If the countdown still does not start, remove the used strip and discard it properly. 3. Repeat the test using a new test strip. 4. If the test still does not start, contact Customer Service.
	Sample applied after meter turns off	1. Remove the used strip and discard it properly. 2. Review the testing instructions. 3. Repeat the test using a new test strip. 4. If the test still does not start, contact Customer Service.
	Defective meter or test strip	1. Remove the used strip and discard it properly. 2. Repeat the test using a new test strip. 3. If the test still does not start, contact Customer Service.

Maintaining the Meter

Replacing the Battery

The meter comes with a CR 2032 lithium (coin cell) battery installed. It provides power for about 1,000 tests.

MEM
mg/dL
104
9:49ᴬᴹ 10-26

• Appears on the display when the battery is low.
• Causes the display light to fail to turn on.

When the battery symbol appears, you may still use the meter and the results will be accurate. The display light will not work. Replace the battery immediately.

When the battery symbol appears alone, the meter is not usable. The meter turns off automatically. Replace the battery immediately.

1. Gently push the battery cover in and up to remove it.

2. If the meter includes a plastic tab, pull on the tab to remove the battery.
   If the meter does not include a plastic tab, push the battery upward to remove it.

3. Insert a new CR 2032, lithium (coin cell) battery: (+) facing up.

4. Slide the battery cover into place until it clicks.

   Note: Dispose of used batteries properly.

5. Press and hold ① to turn the meter on. If the meter does not turn on, check to see that the battery was installed properly.

   If meter turns on, the meter may prompt you to reset the time and date. (See 'Setting Up the Meter' in this user's manual.)

   Note: *Test results will be not be lost even if the meter loses its time and date settings.*

Cleaning the Meter

Avoid getting dirt, dust, blood, control solution, or liquid in the meter test strip port.

Clean the outside of the meter using a damp cloth and mild soap.

Healthcare Professionals:

Acceptable cleaning solutions include:

- 70% isopropyl alcohol, or
- A mixture of 1 part ammonia, 9 parts water, or

Acceptable disinfecting solutions include:

- A mixture of 1 part household bleach, 9 parts water

IMPORTANT:
Do not try to clean the test strip port.
Do not pour liquid into the test strip port or onto the buttons.
Do not immerse the meter in water or other liquid.

Storing the Meter

Store the meter in the carrying case provided.

Specifications

Size	
Length	7.47 cm
Width	Top 5.33 cm
	Bottom 4.32 cm
Depth	1.63 cm
Weight	40 to 46 grams
Power Source	1 CR 2032 Lithium (coin cell) battery
Battery Life	Approximately 1,000 tests
Memory	Up to 450 events, including control solution results, blood glucose results, and other meter information.
Storage Temperature	
Meter	-25 ° to 55 °C (–13 ° to 131 °F)
Test strips	See test strip instructions for use.
Control solution	See control solution instructions for use.

Assay Method	Amperometric electrochemistry
Assay Range	
Blood glucose	See blood glucose test strip instructions for use.
Control Solution Range	
Blood glucose	See blood glucose test strip instructions for use.
Functions	
Blood glucose testing	
Memory	450 events
Glucose averaging	7-, 14-, and 30-day
Control solution marking and testing	
Beeper	**On:** When countdown starts and ends.
Display Light	**On:** Stays on during countdown; turns off 30 seconds after results appear. Stays on while transferring results to a computer.
Data Port	Yes

Operating Range	
Meter temperature	10 ° to 50 °C (50 ° to 122 °F)
System temperature	See operating range of the test strip you are using.
	See test strip instructions for use.
Meter relative humidity	10% to 90%, non-condensing
System relative humidity	10% to 90%, non-condensing
System altitude	Clinical testing demonstrates that altitudes up to 2,195 meters (7,200 feet) above sea level do not affect results

References

1. American Diabetes Association Position Statement:Standards of Medical Care in Diabetes—2010. Diabetes Care 2010;33 (Suppl.1):S11-S61